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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
00/619,412	03/21/96	WOLFENBARGER	L 152 115P DIV

KLIMA AND HOPKINS  
CRYSTAL PLAZA ONE SUITE 905  
2001 JEFFERSON DAVIS HIGHWAY  
ARLINGTON VA 22202-3603

33M1/0916

EXAMINER	
NGUYEN, A	
ART UNIT	PAPER NUMBER
3306	

DATE MAILED:

09/16/97

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

# Office Action Summary

Application No.  
08/619,412

Applicant(s)  
Lloyd WOLFINGER JR.

Examiner  
Nguyen, AT

Group Art Unit  
3306



☒ Responsive to communication(s) filed on Mar 21, 1996

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 59-72 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 59-72 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

ATW

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Double Patenting*

1. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and © may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 59-72 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 5,556,379. Although the conflicting claims are not identical, they are not patentably distinct from each other because omission of an element(s) along with its function(s) is considered to be obvious to one of ordinary skill in the art, in which, the claims become broader, thereby, would extend the monopoly of the patent. The pending claims are apparently broader.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one of ordinary skill in the art would be motivated to make the proposed combination of primary and secondary references. In re Nomiya, 184 USPQ 607 (CCPA) 1975. However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA) 1969.

4. Claims 59-72 are rejected under 35 U.S.C. § 103 as being unpatentable over Draenert (5,192,282) in view of Helenius.

Draenert discloses a process for cleaning bone comprising the steps of selecting a bone and applying a vacuum to the bone in order to remove bone marrow. (See column 2, lines 9-12.) However, Draenert does not specifically disclose the use of a solution to solubilize the bone marrow, even though Draenert discloses that the bone screw can also be used as a drug delivery system (see column 1, lines 56-58) or to allow drainage. Therefore, it is inherent that a solvent can also be applied to the bone grafts and that a process of removing bone marrow elements from the living bone of a patient to produce a substantially cell-free bone matrix is obviously achievable.

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Specifically, Helenius discloses the use of various detergents and solutions in order to clean bone. Thus, it would have been obvious to one having ordinary skill in the art of Draenert to include the detergents disclosed in Helenius in the invention disclosed in Draenert in order to clean bone, since Draenert also discloses that the invention can also be used as a delivery system.

In response to applicant's argument that Draenert is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In this case, it is both.

5. Claims 59-72 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over applicant's admission of the prior art disclosed in the Background of the Invention.

In pages 1-5, especially page 3, of the applicants specification, the applicant admits it is well know to clean smaller bones. The applicant even admits in page 1 that the terminology of "large" is relative. The applicant also admits that the current techniques, which is similar to those disclosed and claimed by the applicant, do not effectively remove bone marrow from the less solvent-accessible cancellous bone spaces within bone grafts because the current precessing techniques rely upon soaking procedures which may or may not include agitation. It is obvious to the Examiner to conclude that it would have been obvious that the effectiveness of the cleaning process is largely depending on the expertised physician and whether or not a physician chooses

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to include agitation or not is optional. Thus this renders the applicant's invention as obvious if not anticipated.

6. Claims 59-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skrinnyuk in view of Morse et al (5,513,662).

Both of these references disclose a method of removing bone marrow via a mechanical means such as a vacuum. Skrinnyuk discloses a method of extracting bone marrow cells and preserving solutions from spongy bone transplant material by vacuum treatment. However, Skrinnyuk does not disclose a method of contacting a bone internal matrix with a solution.

Morse et al, on the other hand, disclose a process of preparing bone for transplantation by cleaning it and decontaminate the bone matrix by introducing a detergent. Therefore, it would have been obvious to one having ordinary skill in the art of Skrinnyuk to apply a detergent to clean a bone.

### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U. S. Patent 4,366,822 discloses a method of removing and separating bone marrow cells by using a bone marrow needle and an aspirator

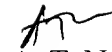
G.B. Patent 964,545 discloses a method of bone grafting in which a tissue is extracted with a non-ionic surfactant solution and then washed with an water solution.


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8. Any inquiry concerning this or earlier communications should be directed to Examiner Nguyen, A. T. at telephone number (703) 308-2154.

In the event if attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Michael Buiz, can be reached at (703) 308-0871.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

  
A. T. Nguyen  
09/12/97

  
Michael Powell Buiz  
Supervisory Patent Examiner  
GAU 3309

9/12/97